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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/259,758	03/01/1999	SUSAN K. BROWN-SKROBOT	VTN-0388	5657

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EXAMINER	
CHORBAJI, MONZER R	
ART UNIT	**PAPER NUMBER**
1744	20

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/259,758	BROWN-SKROBOT ET AL.	
	Examiner	Art Unit	
	MONZER R CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,18-30,33-41 and 51-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,18-30,33-41 and 51-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 7-10, 12, 18-30, 35-41, 51, and 55, 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598).

With respect to claim 51, Clark et al teaches a process and an apparatus for sterilizing a medical device (col.1, lines 7-20), which includes the following concepts: subjecting contact lens (col.7, lines 1-3) to UV in the range of 240 to 280 NM (col.3, lines 60-63), wherein the contact lens is in a hermitically sealed container (col.8, line 33), and further the container is transmissive to at least 50% of UV (abstract, lines 3-5, col.3, lines 53-54, lines 59-63. Thus, such citations include any percentage value for transmissivity. For example, 80% or 50% or the like) in substantially all directions (figure 1, 12) such that package 12 is made of material which will transmit in all directions and capable of holding contact lens (col.6, lines 63-67 and col.7, lines 1-3). In col.7, lines 1-3, Clark states that contact lens packages can be used in the apparatus of figure 1. Then Clark goes on to further show that various materials can be used to design product packages including a contact lens, which can be used in the apparatus of figure 1 (col.7, lines 3-12). As a result, various designs with various materials can be constructed to hold contact lenses according to Clark with or without a foil. Thus, it would have been obvious to one having ordinary skill in the art to modify Clark's contact lens package by designing a container without a foil since Clark discloses the use of various materials in designing such a package.

With regard to claims 7-10, Clark discloses the following: more than 1 radiation source (col.6, line 26), radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims), and flash lamps comprises a reflector and

a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20).

With regard to claim 12, Clark teaches that the radiation is delivered by flash lamps in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37).

With regard to claims 18-30, Clark discloses the following: the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%) such that the range of UV radiation is in the range 240-280 NM (col.3, line 3), container comprises an aqueous solution (col.8, line 4), subjecting a medical device (col.1, lines 13-15) to UV radiation (col.3, lines 60-62) in the range of 240-280 NM (col.3, lines 60-63) using energy value at least 18 mj/cm^2 or 30 mj/cm^2 or 36 mj/cm^2 (col.8, lines 10-12), various time ranges for applying the radiation such that all the values in the claims fall into (col.8, lines 11-12), modifying radiation from a radiation source to eliminate wavelengths which would damage contact lens (col.3, line 36, line 38, and col.4, lines 55-57) such that contact lens are sterilized (col.6, lines 63-65 and col.7, lines 1-3), and container comprises a non-preserved aqueous solution (col.1, lines 10-13).

With regard to claims 35-41, Clark teaches a process and an apparatus for sterilizing contact lens (col.1, lines 7-20 and col.4, lines 55-57) including the following: forming and placing a contact lens (col.7, lines 61-67 and col.8, lines 1-5) in a container, moving the container into an apparatus (col.7, lines 1-3), which is light-tight (col.8, lines 38-39) the use of packages or containers is disclosed made of thermoplastics (col.3,

line 48 and col.1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25), the contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%), container comprises an aqueous solution (col.8, line 4), and radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims).

With respect to claim 55, Clark's container is subjected within a light-tight apparatus (col.8, lines 38-39 and col.7, lines 1-3).

With respect to claims 57-60, Clark et al teaches the following: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18:22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays). In addition; Clark et al teaches of a capacitance and a potential (col.10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is intrinsic in the apparatus of Clark et al to encompass the same values for capacitance and a potential. Furthermore, Clark et al discloses the use of reflectors with enhanced reflection (col.6, lines 42-44); and the reflector minimizes the non-ultraviolet radiation reaching the medical device (col.6, lines 45-48). In addition, see col.8, lines 11-15 for various energy values.

5. Claims 2-6, 11, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Matner et al (U.S.P.N. 5,252,484) and further in view of Shalaby et al (U.S.P.N. 5,422,068).

With respect to claims 2-6 and 11, Clark teaches the following: a sterility assurance level of at 10^-6 (abstract, line 21), all the energy values in the claims fall within the teaching of Clark et al energy value range (col.8, lines 10-12), which contains a specific low range value and a specific high range value, the application of UV radiation to spores (col.9, lines 50-53), the usage of at least one pulsed radiation source (col.6, line 26 and col.3, lines 51-56), various time ranges for applying the radiation which all the values in the claim fall into (col.8, lines 12-19), and pulsed radiation source in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37). However, with regard to claims 52-54, Clark fails to disclose D value for Bacillus Stearothermophilus, ATCC 7953 and how to determine such a value. However, with respect to claims 52-54, Matner teaches a method for determining the efficacy of a sterilization cycle (col.1, lines 7-8) wherein it is known to use Bacillus Stearothermophilus ATCC 7935 to verify how efficient a sterilization cycle is (col.2, lines 35-39). Matner fails to teach D values specific for Bacillus Stearothermophilus, ATCC 7953. With regard to claims 52-54, Shalaby teaches the concept of D-value and its importance to sterility assurance level is explained (col.3, lines 28-65). Also the D-values of Bacillus Stearothermophilus are shown (columns 6-11). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values (col.3, lines 46-57). It would have been obvious to one having ordinary skill in the art to

modify Clark's process by applying UV radiation to Bacillus Stearothermophilus ATCC 7935 in order to determine the sterilizing efficacy since such organisms are recognized as the most resistant form of microbial life (Matner, col.5, lines 53-60 and col.6, lines 3-4).

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Dunn et al (U.S.P.N. 4,910,942).

With regard to claim 13, Clark fails to disclose the use of laser. However, Dunn teaches of a method for sterilizing packaging of medical devices (col.1, lines 17-21) wherein the usage of laser radiation is known (col.2, lines 17-22). It would have been obvious to one having ordinary skill in the art to modify Clark's process to include a laser source in order to sterilize light-transmissive containers (Dunn, col.2, lines 14-15 and lines 18-19).

7. Claims 33-34 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of Heyl et al (U.S.P.N. 5,431,879).

With respect to claim 33, Clark's container (12) consists essentially of thermoplastics (col.7, lines 19-21 and col.7, lines 3-6). However, Clark fails to disclose a container with a lid and a bowl. With respect to claim 33, Heyl's container includes a lid and a bowl (col.9, lines 35-37). It would have been obvious to one having ordinary skill in the art to modify Clark's process to include a container made up of a lid and a bowl.

With respect to claims 34 and 56, Clark discloses at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25), and the apparatus is light tight (col.8, lines 38-39).

Response to Arguments

8. Applicant's arguments filed 09/16/2002 have been fully considered but they are not persuasive.

On page 5 of the response, applicant argues that Clark does not provide any motivation for modifying contact lens packages to modify the foil lid stock to provide for transmissivity in substantially all directions. Clark's contact lens container does not include a foil lid stock as pointed by the applicant. Clark's contact lens container as show in figures 3-6 is made up of polyolefin structure with a foil backing adhered to the bottom (col.7, lines 61-67 and col.8, lines 1-5). However, Clark does explicitly provide a motivation for utilizing various materials to design product packages including a contact lens container (col.7, lines 3-6). This motivation results in modifying (removing or adding) any parts of a contact lens container including the foil backing such that the container is used in the apparatus of figure 1 (col.6, lines 63-67). The package (12) is made of material that will transmit in all directions and is capable of holding contact lens. As a result, one having ordinary skill in the art would have been motivated to modify Clark's contact lens container such that resulting in package (12), which is made of material that transmits in all directions for holding contact lens. Additionally, Clark's contact lens container is made of polyolefin with a foil backing adhered to the bottom. When the container is used in the apparatus of figure 1, the entire top surface and the sides of the container are exposed to radiation such that the container in substantially all directions is exposed to UV light.

On page 5 of the response, applicant argues that the arrows in figures 4 and 6 are shown directed only at the blisters such that Clark does not provide any teaching to modify a contact lens package to provide for transmissivity in substantially all directions. Clark states that contact lens packages can be used in the apparatus of figure 1, which applies UV light in all directions not only at the blisters. Such a package (12) is made of material that will transmit in all directions and is capable of holding contact lens.

Conclusion

9. The prior art made of record but not relied upon is considered pertinent to applicant's disclosure. Clark et al (U.S.P.N. 5,925,885) and Boucher (U.S.P.N. 3,753,651) both shows containers subjected to radiation in substantially all directions.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji MRC
Patent Examiner
AU 1744
October 22, 2002

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